

*Application No. 09/721,904
Amendment dated December 16, 2004
Reply to Non-Final Action of July 20, 2004*

- 9 -

REMARKS

Claims 170, 171, 172, 173, 174, 175, 176, 180, 199, 200, 201, 202, 222, 223, 226, 227, 228, 229, and 230 to 312 are pending in the application.

Claim Amendments

Claims 199 to 202, 222, 223 and 226 to 230 have been amended by deleting reference to SEQ ID NO:5, 6 and 7.

Each of independent claims 170, 199, 222, and 226 has been amended to clarify that the claimed method requires administering the compound or protein, as the case may be, to a mammal. Support for this amendment can be found throughout the specification, and particularly for example, in the application as published under WO99/61468, in each of the fourth and fifth paragraphs on page 7.

Dependent claims 256 to 312 have been added to the specification for consideration of the Examiner, as detailed further below.

No new matter has been added by the amendments submitted herein, as explained further below.

Claim Rejections - 35 USC § 112

Claims 199 to 202, 222, 223 and 226 to 230 stand rejected under 35 U.S.C. 112, second paragraph for reading onto a non-elected embodiment. These claims have been amended by deleting reference to SEQ ID NO:5, 6 and 7, as suggested by the Examiner, thus obviating this rejection.

*Application No. 09/721,904
Amendment dated December 16, 2004
Reply to Non-Final Action of July 20, 2004*

- 10 -

Claim Rejections - 35 USC § 103

Claims 170 to 176, 180, 199 to 202, 222, 223 and 226 to 230 stand rejected as being unpatentable over Diamond *et al.* in view of Julius. Applicants respectfully submit that the amendments made herein obviate the rejection of these claims on this basis.

Each of independent claims 170, 199, 222, and 226 has been amended to clarify that the claimed method requires administering the compound or protein, as the case may be, to the mammal.

As explained in detail on pages 14 to 17 of Applicants' response of April 19, 2004, Diamond *et al.*, suggest that administration of exogenous CD14 can result in binding of CD14 to LPS and therefore interfere with binding of LPS with endogenous epithelial CD14 so as to *reduce* stimulation of defensins by such binding of LPS with endogenous CD14 binding. Diamond *et al.* thus teach away from the administration of CD14 to stimulate defensin expression, and thus the step of administering CD14 to a mammal is not present in the teachings of Diamond *et al.* In fact, the claimed element of administering CD14 is not stated in the outstanding action as being taught by Diamond *et al.* The Julius reference makes no suggestion whatever of the ability of CD14 to stimulate defensin expression, and so administering CD14 to cause defensin expression based on its teachings would be selective and require hindsight available only once one is aware of Applicants' invention, the use of which hindsight is impermissible. Applicants thus respectfully submit that the rejection of these claims on these grounds is obviated, and requests withdrawal of the rejection.

Claim 180 stands rejected as being unpatentable over Diamond *et al.* in view of Julius. Every feature of a claim must be shown in the prior art for the claim to be properly rejected in view thereof. Claim 180 requires administering the compound in the form of an *aerosol*, and neither of the cited references teaches or suggests such a route of administration of CD14. Applicants thus request withdrawal of this rejection.

*Application No. 09/721,904
Amendment dated December 16, 2004
Reply to Non-Final Action of July 20, 2004*

- 11 -

Applicants further submit that because all independent claims are now in condition for allowance, so too are the dependent claims, none of which were rejected on any additional grounds.

Dependent claims 256 to 311 have been added for consideration by the Examiner.

Claims 256 to 274 require that the compound or protein, as the case may be, be administered to a non-neonate human. Basis for this claimed element is provided, for example, in the fifth paragraph on page 28 of the published application where it states that CD14 can be contained in a chewy or malleable product. Such a product is clearly intended for a non-neonate, a neonate being defined by Webster's Online Dictionary as a newborn child, especially one that is less than one month old.

Claims 275 to 286 require the active ingredient to be part of an edible product that readily releases the active ingredient upon mastication. Basis for this claimed element is provided, for example, in the fifth paragraph on page 28 of the published application.

Claims 287 to 293 require the product to be malleable. Basis for this claimed element is provided, for example, in the fifth paragraph on page 28 of the published application.

Claims 294 to 298 require the compound to be topically applied to human skin. Basis for this claimed element is provided, for example, in the penultimate paragraph on page 11 of the published application.

Claims 299 to 303 require the compound to be applied to a wound. Basis for this claimed element is provided, for example, in the penultimate paragraph on page 11 of the published application.

Claims 304 to 312 require the compound to be contained in an ointment. Basis for this claimed element is provided, for example, in the penultimate paragraph on page 11 of the published application.

*Application No. 09/721,904
Amendment dated December 16, 2004
Reply to Non-Final Action of July 20, 2004*

- 12 -

In that all outstanding rejections raised in the outstanding Action have been satisfied, Applicants believe that the application is now in condition for allowance, and request same.

In the event that any issues remain, the Examiner is invited to telephone the undersigned at (416) 865-8121 with any proposal to advance prosecution.

Yours very truly,



December 16, 2004
Date

John C. Hunt
Registration No. 36,424

Torys LLP
Suite 3000
79 Wellington Street West
Box 270, TD Centre
Toronto, Ontario
M5K 1N2
Canada

5013789.3
32388-2002

PAGE 17/17 * RCVD AT 12/16/2004 3:04:15 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-1/25 * DNIS:2730971 * CSID:416 865 7380 * DURATION (mm:ss):04:54 P.17